Claims

1. A liquid pharmaceutical composition comprising follicle-stimulating hormone (FSH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

2. A liquid pharmaceutical composition comprising follicle-stimulating hormone (FSH) or a variant and luteinising hormone (LH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

3. A liquid pharmaceutical composition comprising luteinising hormone (LH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

4. A liquid pharmaceutical composition according to any of the preceding claims, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 150 IU/ml to at or about 1'200 IU/ml.

5. A liquid pharmaceutical composition according to claim 4, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 300 IU/ml to at or about 900 IU/ml.

6. A liquid pharmaceutical composition according to claim 5, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 600 IU/ml.

7. A liquid pharmaceutical composition according to any of claims 2 or 3, wherein the luteinising hormone (LH) is present at a concentration of at or about 150 IU/ml to at or about 1'200 IU/ml.

8. A liquid pharmaceutical composition according to claim 7, wherein the luteinising hormone (LH) is present at a concentration of at or about 300 IU/ml to at or about 750 IU/ml.

9. A freeze-dried formulation comprising follicle-stimulating hormone (FSH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

10. A freeze-dried formulation comprising luteinising hormone (LH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

11. A freeze-dried formulation comprising follicle-stimulating hormone (FSH) or a variant thereof as well as luteinising hormone (LH) or a variant thereof, as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68.

12. The freeze dried formulation according to any of claims 9 to 11, wherein the follicle-stimulating hormone (FSH) is present at a concentration (w/w) of at or about 0.1 to 10 µg/mg of the total formulation.

13. The freeze dried formulation according to claim 12, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.3 to 5 µg/mg of the total formulation.

14. The freeze dried formulation according to claim 13, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.37 to 2 µg/mg of the total formulation.

15. The freeze dried formulation according to any of claims 9 to 11, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 3 µg/mg of the total formulation.

16. The freeze dried formulation according to claim 15, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 1 µg/mg of the total formulation.

17. The freeze dried formulation according to claim 16, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 0.6 µg/mg of the total formulation.

18. A pharmaceutical composition according to any of claim 1 to 17, wherein the surfactant is Pluronic F68.

19. A pharmaceutical composition according to any of the preceding claims, wherein the follicle-stimulating hormone is human follicle-stimulating hormone and/or the luteinising hormone (LH) is human luteinising hormone (LH).

20. A pharmaceutical composition according to claim 19, wherein the follicle-stimulating hormone is urinary human follicle-stimulating hormone and/or the luteinising hormone (LH) is urinary human luteinising hormone (LH).

21. A pharmaceutical composition according to claim 19, wherein the follicle-stimulating hormone is recombinant human follicle-stimulating hormone and/or the luteinising hormone (LH) is recombinant human luteinising hormone (LH).

22. A pharmaceutical composition according to any of the preceding claims, wherein the ratio of FSH to LH is within the range of at or about 6:1 to at or about 1:6.

23. A pharmaceutical composition according to claim 22, wherein the ratio of FSH to LH is within the range of at or about 4:1 to at or about 1:2.

24. A pharmaceutical composition according to claim 23, wherein the ratio of FSH to LH is within the range of at or about 3:1 to at or about 1:1.

25. A pharmaceutical composition according to claim 24, wherein the ratio of FSH to LH is within the range of at or about 2:1 and 1:1.

26. A pharmaceutical composition according to any of the preceding claims, further comprising a bacteriostatic agent selected from phenol and *m*-cresol.

27. A pharmaceutical composition according to claim 26, wherein the bacteriostatic agent is *m*-cresol.

28. A pharmaceutical composition according to claim 27, comprising *m*-cresol at a concentration of at or about 0.3% (mass/mass solvent).

29. A pharmaceutical composition according to any of the preceding claims, further comprising sucrose.

30. A pharmaceutical composition according to any of the preceding claims, further comprising methionine.

31. A pharmaceutical composition according to any of the preceding claims, further comprising a phosphate buffer at a pH of at or about 6.0 to at or about 8.0.

32. A pharmaceutical composition according to claim 31, further comprising a phosphate buffer at a pH of at or about 7.0.

33. A pharmaceutical composition according to claim 32, comprising the following ingredients: rFSH, Pluronic F68, sucrose, methionine, *m*-cresol, and an aqueous phosphate buffer at a pH of at or about 7.0.

34. A pharmaceutical composition according to claim 33, wherein the rFSH is present at a concentration of at or about 600 IU/ml, the Pluronic F68 is present at a concentration of at or about 0.1 mg/ml, the sucrose is present at a concentration of at or about 60 mg/ml, the methionine is present at a concentration of at or about 0.1 mg/ml, the *m*-cresol is present at a concentration of at or about 3 mg/ml, and the phosphate buffer is at or about 10 mM in phosphate.

35. A freeze dried formulation according to claim 11, comprising 32.75 µg of recombinant FSH, 9.0 µg of recombinant LH, 15.0 mg of sucrose, 0.052 mg of $NaH_2PO_4\,H_2O$, 0.825 mg of $Na_2HPO_4\,2H_2O$, 0.05 mg of Pluronic F68 and 0.05 mg of L-methionine.

36. The freeze dried formulation according to claim 11, comprising 65.5 µg of recombinant FSH, 18.0 µg of recombinant LH, 30.0 mg of sucrose, 0.104 mg of $NaH_2PO_4\,H_2O$, 1.65 mg of $Na_2HPO_4\,2H_2O$, 0.10 mg of Pluronic F68 and 0.10 mg of L-methionine.

37. A method for manufacturing a pharmaceutical composition comprising the step of forming a solution of FSH, and a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68, and a liquid diluent.

38. A method according to claim 37, wherein the surfactant is Pluronic F68.

39. A method according to claim 37 or 38, comprising the further step of adding a bacteriostatic agent selected from phenol and *m*-cresol.

40. A method for manufacturing a packaged pharmaceutical composition comprising placing a solution comprising FSH, and a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68, in a vial, ampoule or cartridge.

41. A method according to claim 40, wherein the surfactant is Pluronic F68.

42. An article of manufacture comprising a first container filled with a freeze dried formulation according to any claims from 9 to 11 and a second container comprising a solvent for reconstitution.

43. An article of manufacture according to claim 42, whereby the second container comprises an aqueous diluent containing m-cresol.

44. A method for manufacturing a freeze dried formulation according to any of claims 9 to 11, comprising the step of forming a mixture of FSH with or without LH, or LH alone LH as well as a surfactant selected from Pluronic® F77, Pluronic F87, Pluronic F88 and Pluronic F68, and subjecting the mixture to a lyophilisation.

45. A method according to claim 44, wherein the surfactant is Pluronic F68.